

FDA Targets Gastric Band Weight-Loss Claims

Ready to be the next weight-loss success story?

Let your new life begin!

I lost 90 pounds with the Lap-Band!

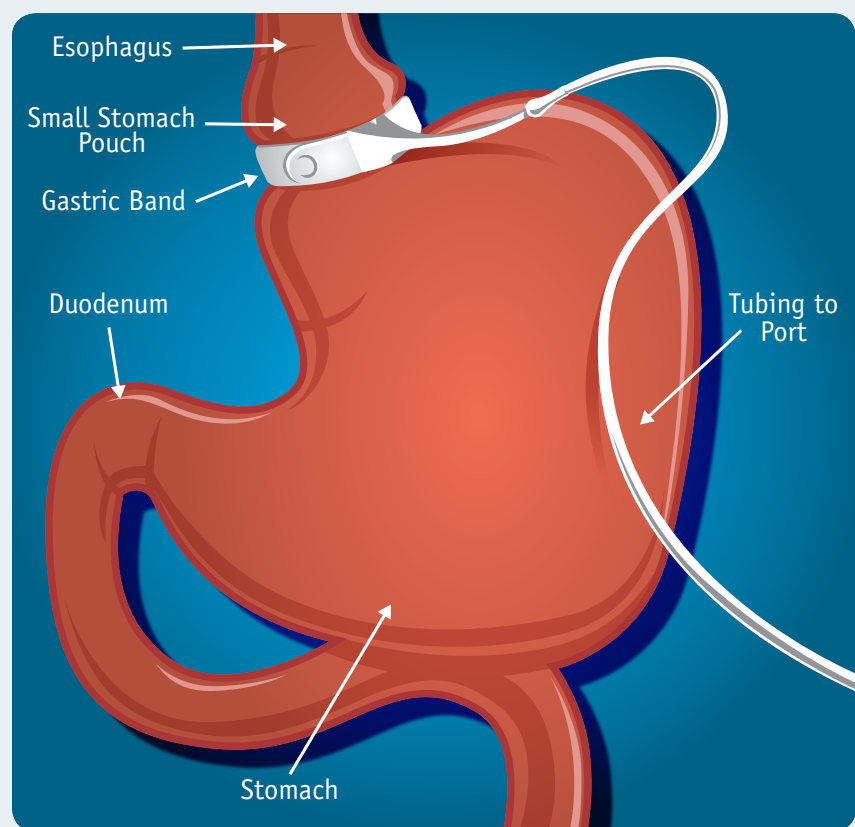
Sounds tempting, doesn't it? The Food and Drug Administration (FDA) has seen many claims similar to the ones above, but there's a catch.

There can be serious risks with the weight-loss surgery and medical implant promoted by these ads, so FDA is taking action.

FDA has warned eight surgical centers and the marketing firm 1-800-GET-THIN LLC in California about misleading advertising of the Lap-Band—a device implanted in a surgery called gastric banding to help adults eat less and lose weight.

The ads—splashed on billboards, bus placards, newspaper advertisements, the Internet and elsewhere—feature slender, smiling men and women claiming they lost massive amounts of weight and gained control of their lives after Lap-Band surgery.

"FDA's concern is that these ads glamorize the Lap-Band without communicating any of the risks," says Steven Silverman, director of the Office of Compliance in FDA's Center for Devices and Radiological Health. "Consumers, who may be influenced by misleading advertising, need to be fully aware of the risks of any surgical procedure."



How Gastric Banding Works

A surgeon places a circular silicone band around the upper part of the stomach, creating a small pouch. The narrowed opening between the pouch and the rest of the stomach controls how fast food passes to the lower part of the stomach. The band is connected with tubing to a button-like part (port) placed close to the skin above the stomach. A doctor can adjust the band, without surgery, by inserting a needle through the skin into the port to add or remove fluid in the band. This changes the size of the opening, which controls how fast food passes into the lower stomach. The band limits the amount of food that can be eaten at one time, helping people to feel full sooner and eat less.

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By federal law, product advertising for certain medical devices, such as the Lap-Band, must contain relevant warnings and information about precautions, side effects, and contraindications (medical reasons that make a treatment inappropriate).

FDA’s warning letters direct the California marketing firm and surgical centers to pull their misleading ads and to notify FDA within 15 working days of action taken to correct them.

Two Gastric Bands Approved

FDA has approved two gastric bands: Lap-Band, by Allergan Inc., and Realize Adjustable Gastric Band, by Ethicon Endo-Surgery Inc. These devices are implanted around the upper part of the stomach to create a “pouch.” The small pouch limits the amount of food that can be eaten at one time, making you feel full faster and potentially lose weight.

Both bands are approved for use in adults age 18 and older who have not lost weight with non-surgical methods, such as diet, exercise or behavior modification, and have

- a body mass index (BMI) (www.nhlbisupport.com/bmi/bmicalc.htm) of at least 40. (BMI is a measure of body fat based on an adult’s height and weight. A 5-foot-6-inch person weighing 248 pounds has a BMI of 40.)
- or -
- a BMI of at least 35 (217 pounds at 5-foot-6 inches) and at least one health condition linked to obesity, such as diabetes or high blood pressure.

Allergan’s Lap-Band is also approved for those with a BMI of 30 to 34 who have a health condition related to their obesity.

The Risks

“Surgery itself has risks, including death, and those risks are heightened for people who are obese,” says Herbert Lerner, M.D., a general surgeon and supervisory medical officer at FDA.

There are risks after the surgery, too, including

- nausea and vomiting
- difficulty swallowing
- gastroesophageal reflux disease (GERD)
- upset stomach or pain
- stretching of the stomach pouch
- stretching of the esophagus
- moving of the gastric band, requiring another surgery to reposition it
- erosion of the band through the stomach wall and into the stomach, requiring another surgery

“Most people lose weight with the gastric band,” says Lerner. “However, one should not assume that a gastric band is a permanent device. A good number of people require another operation to reposition, replace or remove the gastric band sometime during their life due to complications or because they have not lost weight.”

No Binging Allowed

Gastric banding requires a drastic diet change—you need to eat small portions frequently to prevent complications and ensure weight loss, says Lerner. “If you eat or drink more than your stomach pouch can hold, the pouch will stretch and food may back up into the esophagus. You may have nausea and vomiting, and require an adjustment of the band.”

And if patients eat a lot of fattening foods or drink milkshakes or other high-calorie liquids, they may not lose a lot of weight.

If you are considering gastric banding, it is important that you read the information booklet provided by your surgeon and discuss any questions you have with your surgeon before deciding to have surgery. If your surgeon does not provide you with a booklet, ask for one.

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